

Thank you for your time!

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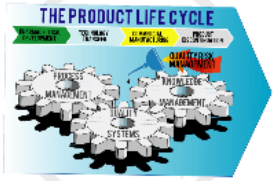






Update on Pharmaceutical Validations





INTRODUCTION



KEY DIFFERENCES



COMMONALITIES





GMP Summit
Valencia, September 25th , 2014

PHARMA-BIOSERV



Presented by:
Victor Sanchez, BSc, MBA, PgDipSc



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Update on Pharmaceutical Validations



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INTRODUCTION

Two different definitions on validation



What about GMPs?

The U.S. FDA and EMA consider **Process Validation** a requirement in both general and specific terms in current Good Manufacturing Practice (cGMP) guidelines and an essential element in the assurance of drug quality.

Drug quality (identity, strength, safety, and efficacy) cannot be solely determined based upon compliance with specifications.



Two different definitions on validation




FDA

Process validation is defined as the collection and evaluation of data, from the process design stage through commercial production, which establishes **scientific evidence** that a process is **capable** of consistently delivering quality product.




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The **documented evidence** that the process, operated within established parameters, can perform **effectively** and **reproducibly** to produce a medicinal product meeting its predetermined specifications and quality attributes.

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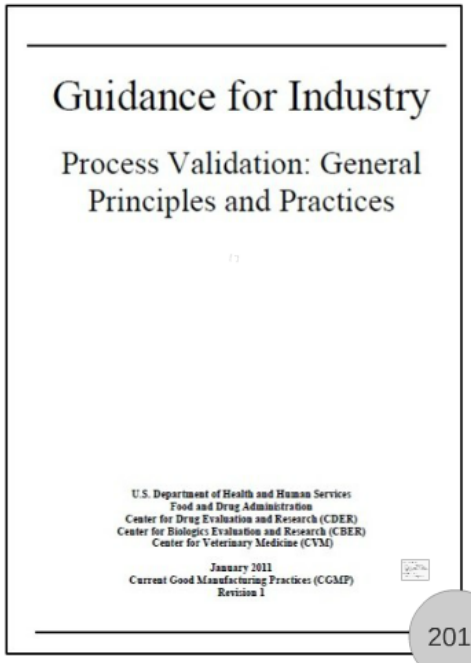
Drug quality (identity, strength, safety, and efficacy) cannot be solely determined based upon compliance with specifications.


So how are they different?

KEY DIFFERENCES







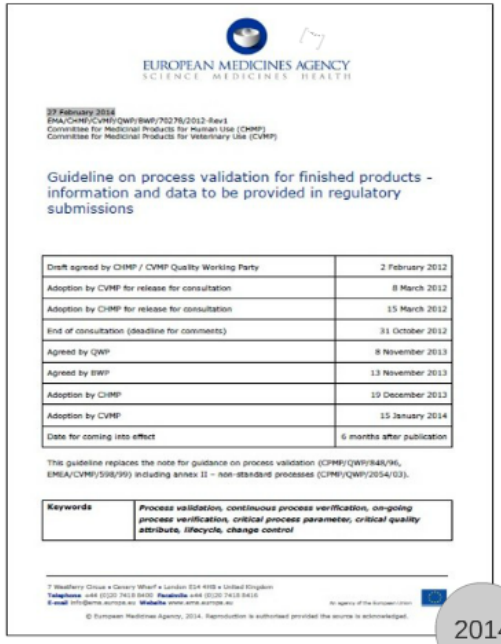
Guidance for Industry

Process Validation: General Principles and Practices

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)

January 2011
Current Good Manufacturing Practices (CGMP)
Revision 1

2011



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27 February 2014
EMA/CHMP/CVMP/QWP/BWP/70278/2012-Rev1
Committee for Medicinal Products for Human Use (CHMP)
Committee for Medicinal Products for Veterinary Use (CVMP)

Guideline on process validation for finished products - information and data to be provided in regulatory submissions

Draft agreed by CHMP / CVMP Quality Working Party	2 February 2012
Adoption by CVMP for release for consultation	8 March 2012
Adoption by CHMP for release for consultation	15 March 2012
End of consultation (deadline for comments)	31 October 2012
Agreed by QWP	8 November 2013
Agreed by BWP	13 November 2013
Adoption by CHMP	19 December 2013
Adoption by CVMP	15 January 2014
Date for coming into effect	6 months after publication

This guideline replaces the note for guidance on process validation (CPMP/QWP/848/96, EMEA/CVMP/598/99) including annex II – non-standard processes (CPMP/QWP/2054/03).

Keywords	*Process validation, continuous process verification, on-going process verification, critical process parameter, critical quality attribute, lifecycle, change control*

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2014

EMA Guideline discusses information and data to be submitted for regulatory submissions

FDA Guidance does not.

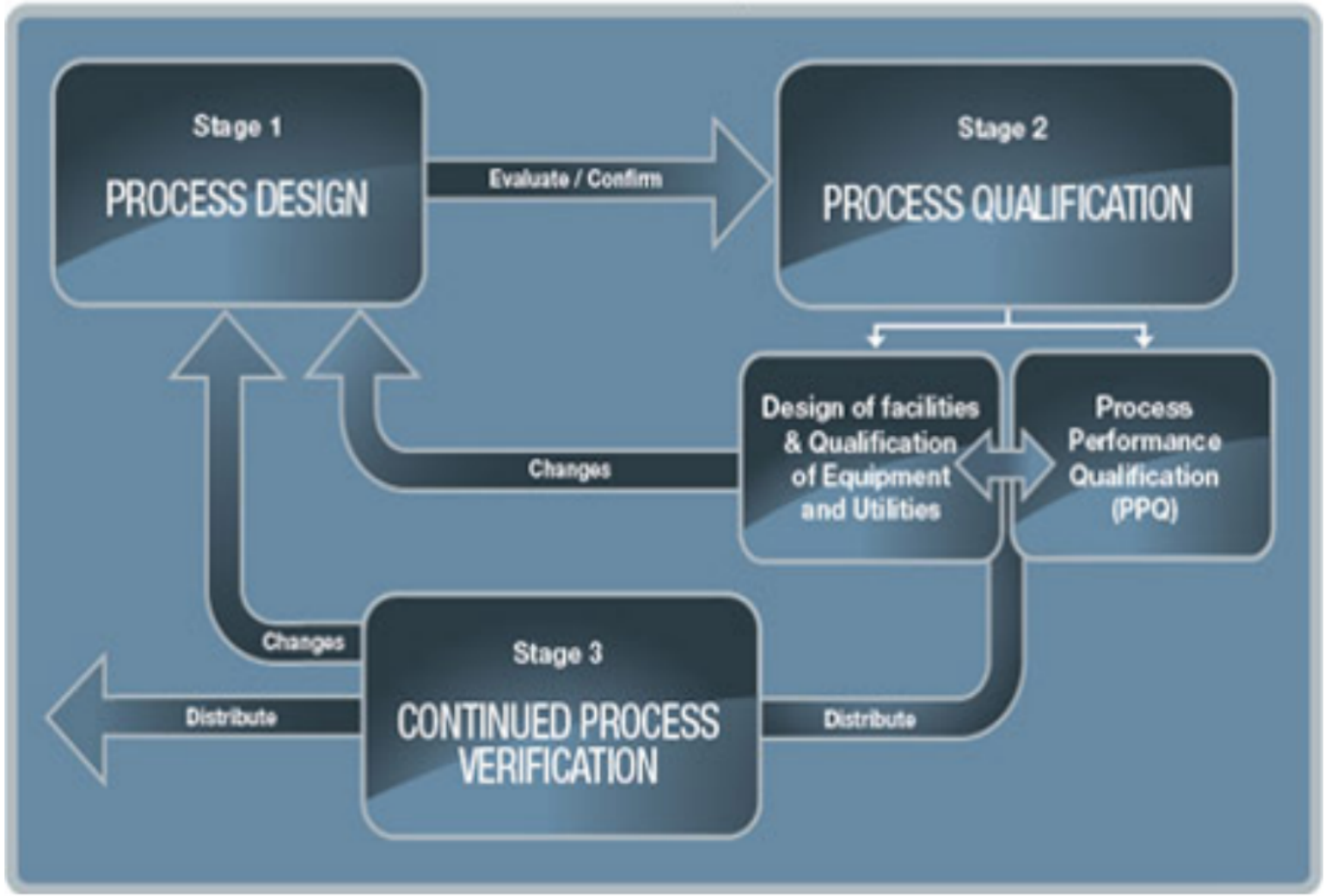
FDA Guidance applies to:

- Human and animal drug products
- Biological and Biotechnology Products
- Active Pharmaceutical Ingredients (APIs)
- Drug constituent of a combination medical device product

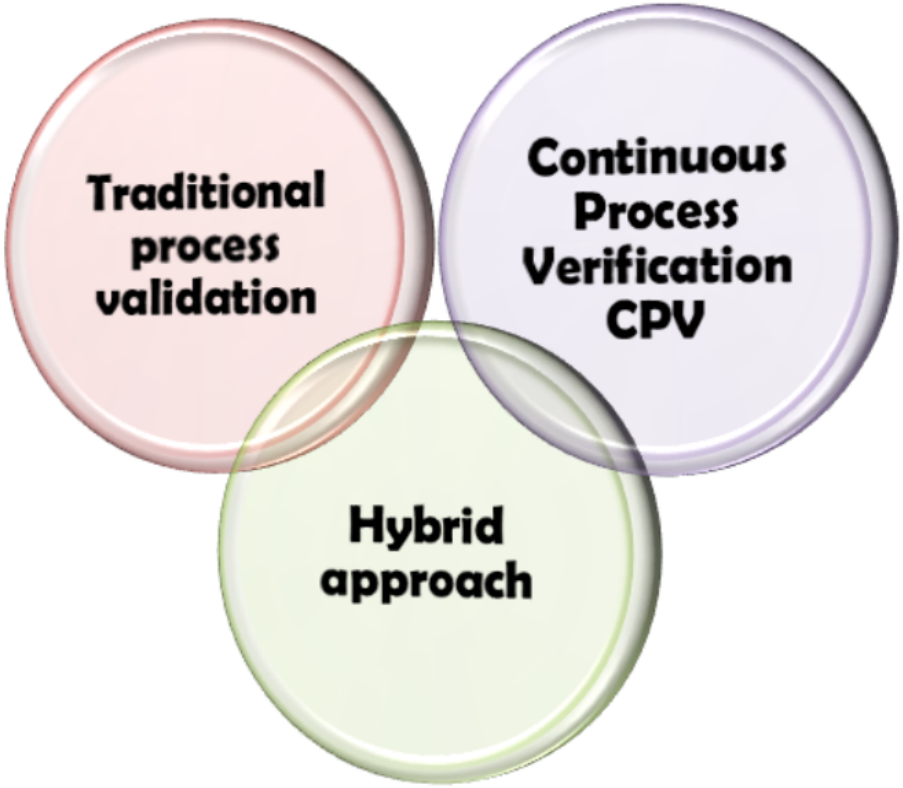
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- Human and animal drug products

There is only ONE approach for the FDA

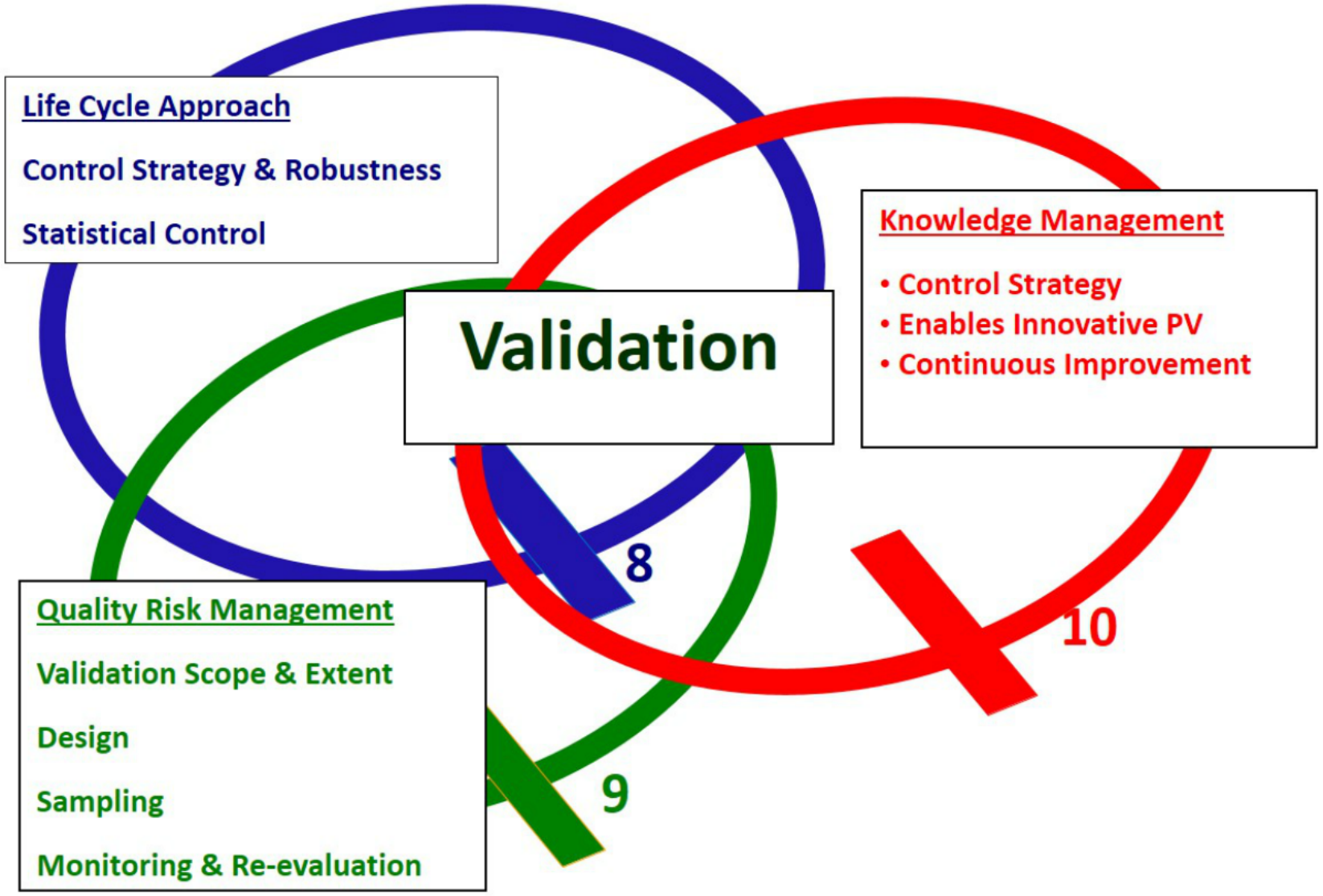


While EMA offers multiple approaches



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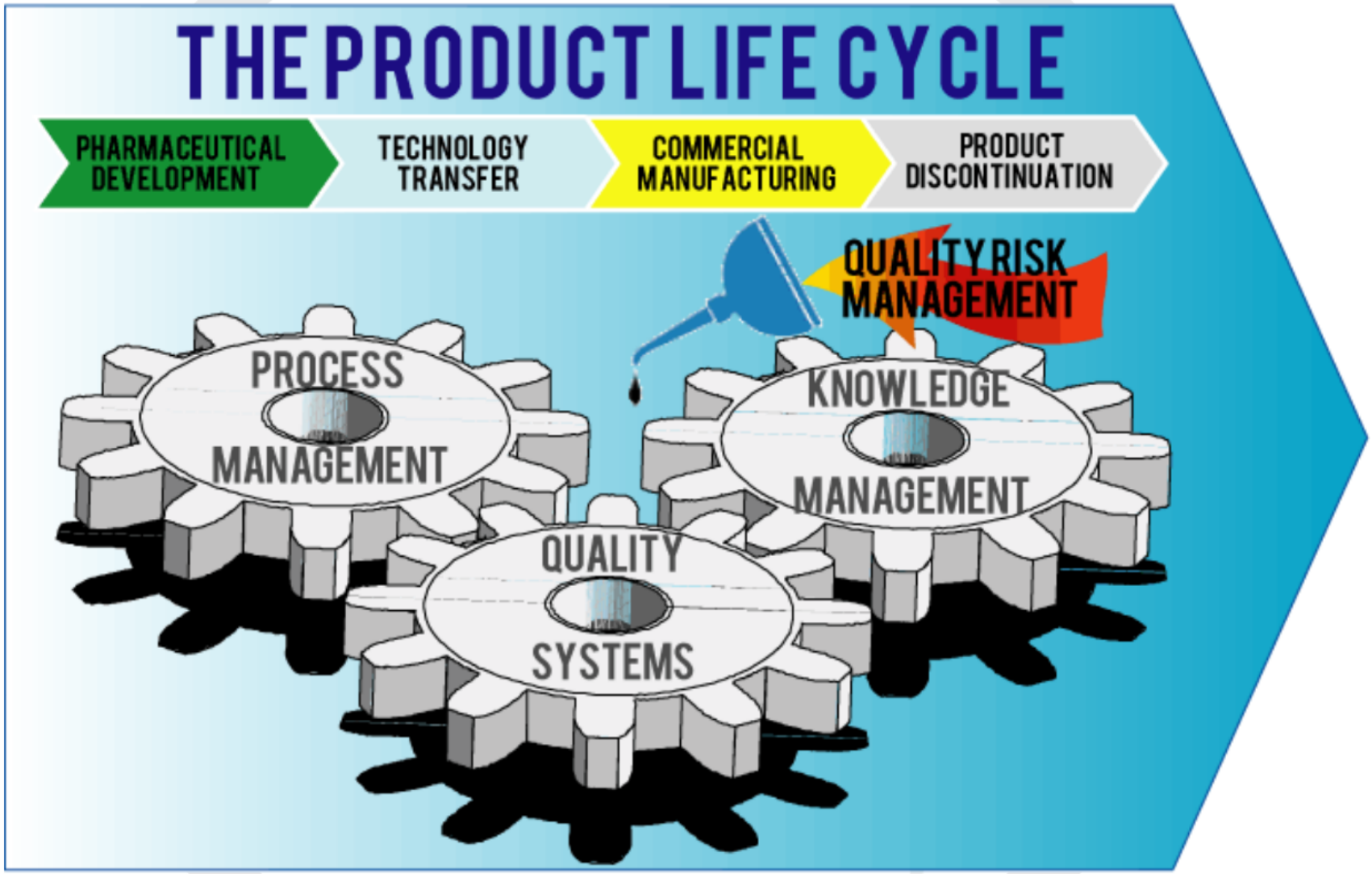


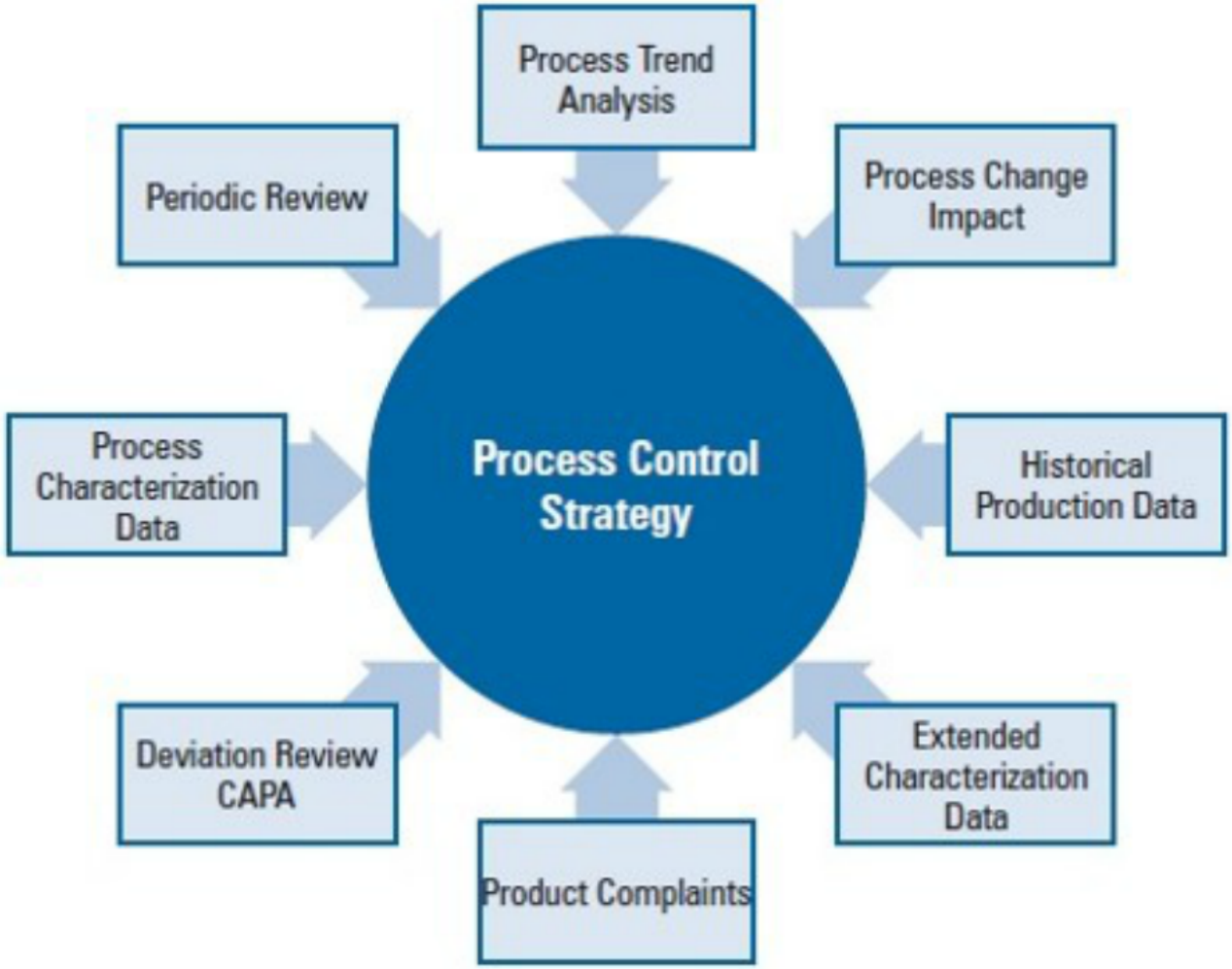


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Validation is a life cycle process



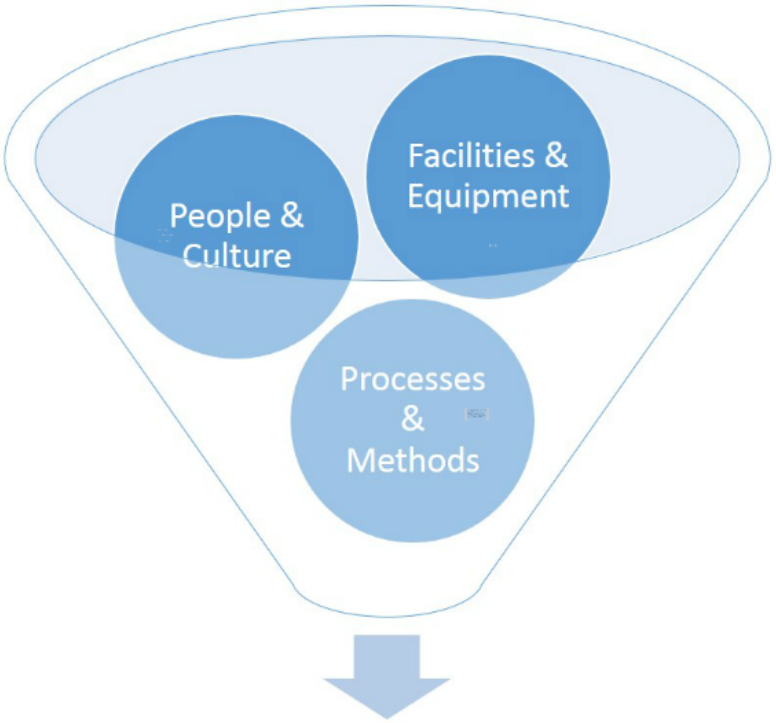

THE PRODUCT LIFE CYCLE
PHARMACEUTICAL DEVELOPMENT
TECHNOLOGY TRANSFER
COMMERCIAL MANUFACTURING
PRODUCT DISCONTINUATION
QUALITY RISK MANAGEMENT
PROCESS MANAGEMENT
KNOWLEDGE MANAGEMENT
QUALITY SYSTEMS


Process Trend Analysis
Periodic Review
Process Change Impact
Process Characterization Data
Process Control Strategy
Historical Production Data
Deviation Review CAPA
Extended Characterization Data
Product Complaints

FUTURE CHALLENGES



Are we (industry & regulators) ready for the new expectations?



Why keep periodic Quality Councils when we should chair 360° Product Reviews/Councils?

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Are our current QA organizations over sighting the entire product life cycle? From Stage 1 to Stage 3?

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Instead of Quality Systems (QS), should we talk about Quality Systems by Design (QSbD)?

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We are clear PAT is not absolutely needed for QbD. But, we also know it is the only way to gain full knowledge from processes in a quick manner.

If Stage 1 is basically linked to QbD, does this mean we need to "upgrade" equipment and install PAT functionality to perform QbD successfully?

Is the industry ready for such a major change?
From People, Technical, and Financial perspectives?

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Is the CTD format good enough to present data?

No. It is possible, but not optimized

Are regulatory inspectors trained as reviewers to understand what they are looking at?
e.g. Do they (we) know enough statistics?

Not sure

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How to start working on Knowledge Management to facilitate CPV?



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